



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<b>(21) International Application Number:</b> PCT/US99/15012  <b>(22) International Filing Date:</b> 1 July 1999 (01.07.99)  <b>(30) Priority Data:</b> 09/110,932                      6 July 1998 (06.07.98)                      US  <b>(71) Applicant:</b> GREAT CIRCLES, INC. [US/US]; 58 East State Street, Montpelier, VT 05601 (US).  <b>(72) Inventors:</b> KOSS, Ronald, L.; R.R.#1, Box 5135, Montpelier, VT 05602 (US). KOSS, Arnold, J.; 152 Kapuahi Street, Makawao, HI 96768 (US).  <b>(74) Agent:</b> BURR, Stephen, P.; Wall Marjama Bilinski & Burr, Suite 400, 101 South Salina Street, Syracuse, NY 13202 (US).		<b>(81) Designated States:</b> AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i>
<b>(54) Title:</b> PRE-PACKAGED FUNCTIONAL FOOD DELIVERY SYSTEM AND METHOD OF ENHANCING THE NUTRITIONAL BENEFITS OF PRE-PACKAGED, DEHYDRATED NUTRITIONAL PRODUCTS  <b>(57) Abstract</b>  <p>A pre-packaged functional food delivery system including a container, a premeasured amount of dehydrated, nutritional substance placed in the container, and at least one capsule placed in the container in contact with the dehydrated, nutritional substance. The capsule includes a sealed wall of water-disintegratable material and oil contained inside the sealed wall. The capsule isolates the oil from the air and dehydrated, nutritional substance until water or a water-based fluid is introduced into the system to disintegrate the sealed wall of the capsule and release the oil to mix with the dehydrated, nutritional substance. Consequently, the flow characteristics and shelf-life of the dehydrated, nutritional substance are better preserved until the introduction of water into the system, thus allowing for the effective and targeted delivery of oils to individuals in both quantity and quality to enhance and support general health and/or specific health conditions.</p>		

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***PRE-PACKAGED FUNCTIONAL FOOD DELIVERY SYSTEM AND  
METHOD OF ENHANCING THE NUTRITIONAL BENEFITS OF  
PRE-PACKAGED, DEHYDRATED NUTRITIONAL PRODUCTS***

***Field of the Invention***

The present invention relates to a pre-packaged functional food delivery system and a method of enhancing the nutritional benefits of prepackaged, dehydrated nutritional products to which water or water-based fluids are added at or substantially immediately before the point of consumption.

***Background of the Invention***

The field of functional food and supplement products is rapidly expanding as more and more people realize the health benefits attributable to certain fats derived from oils. These products are beneficial not only to support health recovery (e.g., after major surgery or chemotherapy treatments), but also to maintain biochemical homeostasis.

It is now known that essential fatty acids (EFA) are integral to maintaining human health. It has been reported that specialized long chain omega-3 fatty acids, such as those derived from sea algae and/or fish oils, may reduce the risk of cardiovascular death in middle aged American men by about 40%. Other data suggests that omega-3 fatty acids may decrease cancer mortality.

Similarly, other omega-3 fatty acids such as eicosapentaenoic acid (EPA) appear to be particularly important as an anti-inflammatory agent and for support of

enhanced immune system functioning. In one study patients administered an enteral feeding formula containing structured lipids and fish oil had 70 percent fewer infections and a 22 percent reduction in the mean length of hospital stay.

Other essential fatty acids, such as GLA (Gamma-Linolenic Acid), have been proven to support joint health and may alleviate the pain and discomfort of rheumatoid arthritis. Research also suggests a favorable impact of GLA upon cholesterol reduction, dry skin (eczema and dermatitis), diabetic neuropathy, and PMS and other hormonal imbalances. Plant seed oils such as borage, evening primrose and black currant are known to be good sources of GLA.

In addition to oils, which provide EFA's of the type described above, there are other powerful nutrients that provide significant health benefits, both during health maintenance and in health recovery. L-Glutamine is but one example of a protein-based nutrient that has been proven to support regeneration of gastrointestinal mucosal cells and is an important oxidative fuel for rapidly dividing cells such as enterocytes, colonocytes and lymphocytes .

Despite the established benefits attributable to essential fatty acids, food manufacturers have made virtually no progress in incorporating such nutrients into convenient, ready-to-consume food and drink products. To the extent such essential fatty acids are found in convenience food and drink delivery systems, their quantities are so small as to be marginal or insufficient to provide adequate supplementation to effect the structure and function of the body positively. This latter problem is particularly meaningful in the case of senior citizens and children, both of whom

often rely upon convenience foods for a major part of their nutrition. This latter problem is also particularly meaningful for individuals recovering from illness, accidents, surgery and eating disorders, since it is essential to maximize both the caloric effect and the levels of specific functional nutrients of what little food such people may be able to eat during the recuperative process.

Generally speaking, supplemental nutrients have been delivered to the consumer in either liquid or powder form. The more popular delivery approach is in liquid "shake" form, wherein the nutrients are delivered by retorted or aseptically processed sweetened and fortified liquids. Brands such as Ensure® and Slim Fast® dominate this category. These products are often used by individuals desiring a convenient and complete meal supplement, and as such are offered in limited sweet flavors, such as vanilla, chocolate and strawberry.

The delivery of supplemental nutrients in powder form is more desirable from a manufacturing and packaging standpoint, since the liquid component of the consumable product is not added until the point of consumption. Accordingly, the overall weight of the product can be reduced significantly, thus making it more economical to package and ship.

While dry ingredient nutrient delivery systems, such as powders, are convenient and economical, the percent of "natural" oils that can be added to the dry ingredients to achieve optimal functional benefits and caloric value is limited to 5% - 7% by weight (the upper limit may fluctuate depending upon the types of dry ingredients and oils used). The reason for this is that the dry ingredients can absorb

only so much oil before the ingredients become sticky or gummy, thus adversely affecting the flow characteristics of the dry ingredient powder. The ingredients must be free flowing (i.e., substantially non-agglomerating) to allow mass production using conventional powder-handling processing equipment.

5           While the addition of 5% to 7% oil does not present a problem in most food supplements targeted at healthy people, it may be a significant limitation in the functional foods category where delivering higher levels of essential fatty acids are needed and typically unavailable in basic, conventional powdered food stuffs. These functional foods are crucial for health recovery, and are beneficial for health  
10 maintenance. It is often necessary in health recovery and geriatric situations to deliver high caloric value and specific essential fatty acid nutrition. The 5%-7% limitation discussed above is a significant impediment on using dry/powder delivery systems.

          To date, the conventional food science response to adding fats to dry  
15 ingredient food products has been either hydrogenation and/or limiting the percentage of liquid oils to less than 7 percent by weight. With hydrogenation, a hydrogen molecule is added to the natural unsaturated fatty acid molecules of the oil. This results in the creation of an unnatural fatty acid, causing the oil to become solid or semi-solid. The "solidified" oil is then spray dried and used to create calorie dense  
20 powders. Unfortunately the technology of hydrogenation changes the configuration of the fatty acid from the natural cis to trans. Trans fatty acids and hydrogenated oils have been linked to abnormal sperm production, decreased testosterone in men, heart

disease, increased cholesterol, prostate disease, obesity and suppression of the immune system.

Given the medically established deleterious effects of hydrogenated oils, there are no healthful and natural means to deliver functional quantities (i.e., >5%-  
5 7%) of oils in a convenience food delivery system. As a result the powder nutrient delivery system format is limited in its ability to offer complete essential fatty acid nutrition to individuals such as seniors, children and patients challenged by illness, accident and surgery.

Another limiting factor on the use of oils in a dry ingredient delivery system  
10 is the instability of those ingredients during mixing of the powder product and subsequent storage. Dry ingredient products typically require a 12-month shelf life to be commercially viable. Polyunsaturated oils have a tendency to degrade due to oxidation and become rancid. It is commonly known that oil rancidity can impart off flavors and may limit the minimum required shelf life of a product. In the case  
15 of a functional food, a consumer may be dependent upon receiving functional levels of specific nutrients that are derived from oils. A manufacturer of functional foods thus faces the added dilemma of insuring (i) that oxidation does not erode the levels of essential fatty acid nutrients represented on the product label and (ii) that it does not sell rancid products that may present a health risk to a wide range of consumers,  
20 some of whom may have compromised immune systems and other health problems.

It would be desirable to provide a prepackaged functional food delivery system that can deliver, in dry form, powdered nutritional substances containing

oil(s) without adversely affecting the flow characteristics or shelf-life of the powder.

It would also be desirable to provide a method of enhancing the nutritional benefits of prepackaged, dry nutritional products, to which water or water-based fluids are added at or substantially immediately before the point of consumption, without adversely affecting the flow characteristics or shelf-life of the dry products.

### *Summary of the Invention*

It is an object of the present invention to provide a practical means of transforming prepackaged, dry (dehydrated) ingredient convenience foods into functional food delivery systems by introducing, during manufacturing prior to packaging, specific encapsulated oil(s) into the dry ingredient mixture. The use of encapsulated oil(s) allows for the oil portion of the consumable product to exceed 5-7 percent by weight without adversely affecting the dry nature of the ingredients, and hence the ability to package the product without the agglomeration of ingredients (i.e., the flow characteristics of the dry ingredients are preserved). The use of encapsulated oil(s) also allows for the oil portion of the consumable product to be (i) all natural and shelf-stable without the need for hydrogenation, and (ii) delivers specialized, targeted essential fatty acids to meet the nutritional needs of individuals in a variety of health stress circumstances.

In accordance with a preferred embodiment of the present invention, a prepackaged functional food delivery system is provided that includes a container, a premeasured amount of dehydrated, nutritional substance placed in the container,

and at least one capsule placed in the container in contact with the dehydrated, nutritional substance. The capsule includes a sealed wall of water-disintegratable material and oil(s) contained inside the sealed wall. The capsule isolates the oil(s) from the air and dehydrated, nutritional substance until water or a water-based fluid is introduced into the system to disintegrate the sealed wall of the capsule and release the oil(s) to mix with the dehydrated, nutritional substance. Consequently, at least one of the flow characteristics and shelf-life of the dehydrated, nutritional substance is preserved until the introduction of water into the system.

In accordance with another preferred embodiment of the present invention, a method is provided that enhances the nutritional benefit of prepackaged, dehydrated functional food products to which water or water-based fluids are added at or substantially immediately before the point of consumption. The method comprises the steps of placing a dehydrated, nutritional substance within a container, placing at least one capsule within the container in contact with the dehydrated, nutritional substance, the capsule including a sealed wall of water-disintegratable material and oil(s) contained inside the sealed wall, and sealing the container or encompassing the container within packaging in order to maintain the dehydrated, nutritional substance and capsule within the container. The capsule isolates the oil(s) from the air and dehydrated, nutritional substance until water or a water-based fluid is introduced into the system to disintegrate the sealed wall of the capsule and release the oil(s) to mix with the dehydrated, nutritional substance. Consequently, at least one of the flow

characteristics and shelf-life of the dehydrated, nutritional substance is preserved until the introduction of water into the system.

In accordance with a more preferred embodiment of the invention, the oil(s) is(are) non-hydrogenated.

5           As used herein, "functional foods" are foods that offer macronutrients (e.g., fats, proteins, carbohydrates), micronutrients (e.g., vitamins, minerals), or nutrients (nutrients that affect health but for which no physiologic need has been determined) at levels much greater than can be expected through normal dietary intake alone. "Dehydrated" means dried to the point of substantially no free water content, by any  
10       known means such as spray drying, freeze drying or dehydrating. "Water-disintegrateable" means the ability of a capsule material to dissolve, melt, or otherwise break apart once introduced into water. "Water-based" means any substance that includes water as its main liquid ingredient. "Nutrients" mean any substances that provide nourishment. "Oil" or "oils", for the purposes of this  
15       disclosure, are considered analogous to "fat" or "fats".

#### ***Detailed Description of the Preferred Embodiments***

The present invention can be used with any type of dry food or drink product that is intended to deliver nourishment to the consumer. There is no limitation on  
20       the types of dry or dehydrated foods that can be used in connection with the invention, so long as the foods are prepackaged in ready-to-serve or ready-to-prepare containers. The consumer must be able to simply add water or water-based liquids

to the dehydrated food for preparation and consumption. It is preferred that the dehydrated foods be of the type requiring hot water hydration, as the heat associated with the water is helpful in disintegrating the capsule that holds the oil(s).

5 There are only minor limitations on the oils that can be used in connection with the present invention. One limitation is the taste of certain oils. Specifically, the contents of the capsule, once combined with the base dehydrated food substance, should not cause an offensive odor in the prepared food product to be consumed. This would adversely affect the palatability of the food product from the viewpoint of the consumer.

10 Another limitation is merely one of commercial availability, in that the material of the capsules must be disintegratable in water or water-based liquids. Most capsule materials currently available are water soluble, and thus will disintegrate when immersed in water. Increasing the temperature of the water helps the disintegration process, although we expect that cold water-soluble capsule materials will be available in the near future.

15 The combined dry mixture of dehydrated food substance and capsules containing the oil(s) should be placed in a container for storage until use. Preferably, the container is a single use container, so that the amount of encapsulated material can be properly matched to a premeasured amount of dehydrated food substance. This insures that the overall functional food product ultimately consumed includes the correct amount of each preselected ingredient. This also removes any guess-work that would otherwise be required by the consumer in formulating the capsules with the base food powder. While any container can be used, it is preferred

that the dry ingredients and capsule(s) be placed in a pouch for introduction into a cup or bowl to receive the water component of the final food or drink product, or in a disposable serving utensil that will also receive the water component.

5 The present invention provides, for the first time, shelf stable essential fatty acid-containing functional food powder products. The use of encapsulation allows the oil(s) to be delivered in a long-lasting, shelf stable powder product that can be manufactured using existing powder handling equipment. The encapsulation technique described herein effectively shields the oil(s) from the base food powder until or immediately before the point of preparation for consumption. Incorporation  
10 of these encapsulated nutrients into well accepted consumer convenience foods, such as a cup-of-soup or cup-of-cereal type products, allows the nutrients to maintain their efficacy for a prolonged time period and then be delivered at the point of consumption in concentrations heretofore not commercially possible.

The present invention provides, for the first time, a powder or dry ingredient  
15 delivery system that can be manufactured with non-hydrogenated oils containing essential fatty acids as a percentage of product weight at 5%-7% and greater. Also, for the first time, this level of essential fatty acid nutrition can be delivered in a dry ingredient delivery system with a greatly reduced risk of product spoilage due to oxidative rancidity of the oil.

20 Individuals recovering from illness, accident, surgery and eating disorders, as well as seniors and children, will now have a wider variety of functional food choices that deliver nutrient and calorie dense supplementation that incorporate, for

example, therapeutic levels of otherwise unstable polyunsaturated oils such as DHA (docosahexaenoic acid). Additionally, given the reliance on convenience foods in our fast paced lifestyles, the ability to now conveniently deliver more shelf stable, balanced, and high quality essential fatty acids to otherwise healthy children will be paramount in supporting their proper development. Given the preponderance of unhealthy fats (i.e., hydrogenated) that have infiltrated the western diet, the present invention will help to counterbalance this trend by giving manufacturers the opportunity to transform their products into functional foods to promote and maintain health. The present invention allows for "smart" supplemental nutrition to come into hospitals, public schools cafeterias, lunch boxes, nursing homes, vending machines, backpacks and supermarkets, and deliver complete and specialized functional food products that require the consumer to do no more than open, add water and consume.

While the present invention has been particularly shown and described with reference to the preferred mode as illustrated in the drawing, it will be understood by one skilled in the art that various changes in detail may be effected therein without departing from the spirit and scope of the invention as defined by the claims appended hereto. For example, while the preferred embodiment relates to the encapsulation of oil(s), it is believed that the techniques described hereinabove apply equally as well to other supplemental nutrients, such as certain proteins, that present the same or similar problems when pre-mixed with powdered food stuffs.

**What is claimed is:**

1           1.     A pre-packaged functional food delivery system, comprising:  
2                 a container;  
3                 a premeasured amount of dehydrated, nutritional substance placed in said  
4 container; and  
5                 at least one capsule placed in said container in contact with the dehydrated,  
6 nutritional substance, said capsule including a sealed wall of water-disintegratable  
7 material and essential fatty acid-containing oil inside the sealed wall;  
8                 wherein the capsule isolates the oil from the air and dehydrated, nutritional  
9 substance until water or a water-based fluid is introduced into the system to  
10 disintegrate the sealed wall of the capsule and release the oil to mix with the  
11 dehydrated, nutritional substance, whereby at least one of the flow characteristics  
12 and shelf-life of the dehydrated, nutritional substance is preserved until the  
13 introduction of water into the system.

1           2.     The pre-packaged functional food delivery system of claim 1,  
2 wherein said dehydrated, nutritional substance is in powder form.

1           3.     The pre-packaged functional food delivery system of claim 1,  
2 wherein said oil is non-hydrogenated.

1           4.     The pre-packaged functional food delivery system of claim 1,  
2 wherein said water-disintegratable material comprises gelatin.

1           5.     A method of enhancing the nutritional benefit of prepackaged,  
2 dehydrated functional food products to which water or water-based fluids are added  
3 at or substantially immediately before the point of consumption, said method  
4 comprising the steps of:  
5           placing a dehydrated, nutritional substance within a container;  
6           placing at least one capsule within the container in contact with the  
7 dehydrated, nutritional substance, the capsule including a sealed wall of water-  
8 disintegratable material and essential fatty acid-containing oil inside the sealed wall;  
9 and  
10          sealing the container or encompassing the container within packaging in  
11 order to maintain the dehydrated, nutritional substance and capsule within the  
12 container;  
13          wherein the capsule isolates the oil from the air and dehydrated, nutritional  
14 substance until water or a water-based fluid is introduced into the system to  
15 disintegrate the sealed wall of the capsule and release the oil to mix with the  
16 dehydrated, nutritional substance, whereby at least one of the flow characteristics  
17 and shelf-life of the dehydrated, nutritional substance is preserved until the  
18 introduction of water into the system.

1           6.     The method of claim 5, wherein the dehydrated, nutritional substance  
2 is in powder form.

7.     The method of claim 5, wherein the oil is non-hydrogenated.

1           8.     The method of claim 5, wherein the water-disintegratable material  
2 comprises gelatin.

1           9.     A method of increasing the amount of oil present in a prepackaged,  
2 powdered functional food product above and beyond the maximum amount of oil  
3 that can be absorbed by the powder without adversely affecting the flow  
4 characteristics of the powder, said method comprising the steps of:  
5           adding at least one capsule to the powder, the capsule including a sealed wall  
6 of water-disintegratable material and additional oil contained inside the sealed wall;  
7 and  
8           placing the powder and capsule in a container;  
9           wherein the introduction of water or water-based fluids to the powder and  
10 capsule at or substantially immediately before the point of consumption disintegrates  
11 the sealed wall of the capsule and releases the additional oil to mix with the powder,  
12 whereby the total amount of oil in the resultant mixture to be consumed exceeds said  
13 maximum amount.

10. The method of claim 9, wherein the oil is non-hydrogenated.

1 11. The method of claim 9, wherein the water-disintegratable material  
2 comprises gelatin.

1 12. A method of introducing a supplemental nutrient into a prepackaged,  
2 powdered food product while impeding nutritional degradation of the food product  
3 due to deterioration of the supplemental nutrient, said method comprising the steps  
4 of:

5 adding at least one capsule to the powder, the capsule including a sealed wall  
6 of water-disintegratable material and a supplemental nutrient contained inside the  
7 sealed wall; and

8 placing the powder and capsule in a container;

9 wherein the capsule isolates the supplemental nutrient from the powder until  
10 water or a water-based fluid is introduced to disintegrate the sealed wall of the  
11 capsule and release the supplemental nutrient to mix with the powder, whereby the  
12 nutritional value of the food product is preserved until the introduction of water into  
13 the system.

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/15012

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 7 A23P1/00 A23P1/04

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A23P A23L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	page 3, line 51 - page 5, line 20; example 2 page 4, line 54 - line 58	9-11
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Y	page 1, line 13 - line 22 page 1, line 34 - line 38 page 2, line 124 - page 3, line 4 page 3, line 64 - line 76 examples 4, 7, 10 claim 1	9-11
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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# INTERNATIONAL SEARCH REPORT

International Application No

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Information on patent family members

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